

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Marked-up Version Showing Changes.**"

The Examiner is invited to telephone the undersigned if doing so will assist in the examination of the application.

Respectfully submitted,

DORSEY & WHITNEY LLP

Date:

January 17, 2002

By:

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MARKED-UP VERSION SHOWING CHANGES

IN THE SPECIFICATION

Priority Claim

The above-identified patent application, claims priority to German Patent Application No. 101 01 932.7, filed on January 17, 2001.

[This object is solved by the subjects of the independent claims.]

On page 3, in line 6, please replace the sentence as follows:

Due to the suction of the tissue at the site of product delivery in accordance with the invention, the [used] user

On page 4, in lines 1, please replace the sentence as follows:

In alternative, particularly preferred [example] exemplary embodiments, the suction chamber is formed by means of a

On page 4, line 11, please replace the sentence as follows:

of the administering device of a separate suction piece, in preferred [example] exemplary embodiments. Since the

On page 11, line 4, please replace the sentence as follows:

3 dispensing means, (injection needle, pressure injector, etc.)

Please substitute the following pages 5-9 for originally filed pages 5-9:

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BRIEF DESCRIPTION OF THE DRAWINGS

Preferred [example] embodiments of the invention will now be described by way of [example] exemplary embodiments. The features disclosed in the [example] exemplary embodiments, each individually and in every disclosed combination, advantageously develop the subjects of the claims. [There is shown:]

Figure 1 depicts a suction piece detachably connected to an administering device;
Figure 2 depicts the suction piece from Figure 1 in an individual representation;
Figure 3 depicts an administering device comprising an integrated suction chamber;
Figure 4 depicts an administering device comprising a pump in a first embodiment;
Figure 5 depicts the administering device from Figure 4 comprising a pump in a second embodiment, in a starting position;
Figure 6 depicts the administering device from Figure 5 comprising the pump in an end position;
Figure 7 depicts an administering device comprising a bilaterally acting pump for delivering product; and
Figure 8 depicts an administering device comprising a bilaterally acting pump for injecting an injection needle and for delivering product.

DETAILED DESCRIPTION

Figure 1 shows a longitudinal section of a device for administering an injectable product, for example insulin, while [it] the product is being administered. The device is formed by an injection pen, such as is known to the person skilled in the art. Of the device, only a casing 1, a product reservoir 2 and a dispensing means 3 are shown. The product reservoir 2 is formed by a conventional ampoule comprising a piston accommodated in it. The ampoule is inserted in a receptacle of the casing 1 in a known way. The dispensing means is formed as a conventional injection needle which is connected to the product reservoir 2 in a way known in its own right, and which protrudes straight

from the casing 1 at a proximal end.

A suction piece 4 is detachably screwed on at the proximal end of the casing 1. The suction piece 4, which may be repeatedly connected to the casing 1, is shown individually in Figure 2 [,] detached from the administering device.

The suction piece 4 is sleeve-shaped as one piece, and forms a connection part 5 at an end facing the administering device. At a proximal end facing away from the administering device, the suction piece 4

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forms a suction chamber V [, 6] comprising a hollow space [V] generally defined by means of a wall 6 . The proximal end of the suction piece 4 includes a chamber opening rim 6' extending generally circumferentially around the opening into the suction chamber V. [, when]] When the device is placed on the surface of the tissue i.e., when the rim 6' is placed against the skin, the tissue surface and wall 6 fully define the suction chamber V. [via an exposed chamber opening rim of the suction chamber V [,6].] The connection part 5 and the wall 6 of the suction chamber V [, 6] are separated from each other by a partition extending radially to the longitudinal axis of the suction piece 4. A passage 7 extends through the partition, co-axially to the central longitudinal axis. The passage 7 is sealed air-tight by a seal 8 arranged in the passage, a septum. The partition together with the seal 8 forms an air-tight separating area between the distally open connection part 5 and the proximally open suction chamber V [,6]. Corresponding to preferred example embodiments, the suction piece 4 can be realised as an otherwise one-part plastic injection part by extrusion-coating the seal 8.

In order to connect the suction piece 4 to the administering device, the suction piece 4 together with the connection part 5 is screwed onto the proximal end of the device. In the course of screwing the suction piece 4 and the connection part 5 on, the injection needle 3 is pushed through the passage 7 and so penetrates through the seal 8. After the needle 3 has pierced the seal 8, the seal 8 surrounds the injection needle 3 air-tight.

Instead of in the passage 7, the seal 8 can also be arranged elsewhere, it must only be ensured that the passage 7 for the injection needle 3 or another dispensing means is sealed air-tight, for the purpose of evacuating the suction chamber V [,6]. This can, for example, also be achieved by arranging the seal between the proximal end of the casing 1 and the rear outer area of the suction piece 4, at which the passage 7 opens, or by sealing in the area of the screw connection between the casing 1 and the suction piece 4.

A passage 9 leads through the wall 6 of the suction chamber V [6], i.e. the passage 9 opens at one end in the suction chamber V [6], and at its other end on an outer surface area of the suction piece 4. The passage 9 serves to connect a pump [,] for evacuating the suction chamber V [6].

To administer the product, the administering device is placed on the tissue 10 at the desired point of injection via the exposed chamber opening rim 6' of the suction piece 4. In this state, the suction chamber V [6] is substantially sealed [off from tissue 10] . A slight distance remains between the surface of the tissue and the tip of the injection needle 3. In this position, the suction chamber V [6] is evacuated via the passage 9, i.e. a partial vacuum with respect to the surroundings is generated in the chamber V . Due to the partial vacuum, the tissue is suctioned

into the suction chamber V [6] toward the tip of the injection needle 3. A bulge of tissue is formed under the tip of the needle. In the preferred application, subcutaneous injection, the bulge of tissue is a fold of skin. With increasing evacuation, the bulge of tissue swells further up and is suctioned beyond the tip of the needle [via the injection needle] . In other words, the injection needle 3 penetrates into the bulge of tissue. This state is shown in Figure 1. The product can now be delivered from the reservoir 2 through the injection needle 3 into the tissue 10.

Figure 3 shows the proximal end of an administering device comprising an integrated suction chamber V [6]. As opposed to the [example] exemplary embodiment in Figures 1 and 2, the chamber wall 6 together with the passage 9 is an integral component of the casing 1 of the device. In the [example] exemplary embodiment of Figure 3 , the casing 1 and the chamber wall 6 are injection-moulded as one piece from a plastic material. The injection needle 3 is surrounded air-tight by the plastic material; it can, for example, be inserted into the injection mould during manufacture and extrusion-coated with the plastic material. In this way, a disposable syringe in particular can be manufactured. In the case of a reusable injection device comprising an integrated suction chamber V [6], a seal would again have to be provided in a passage for the injection needle 3 or another dispensing means, for example a high pressure injector, as in the [example] exemplary embodiment in Figures 1 and 2.

Figure 4 shows the device from Figures 1 and 2, further comprising a connected pump 11. The pump 11 is a piston pump comprising a piston 15 accommodated linearly [movable] moveably in a cylinder 14. A piston rod 16 projects from a rear side of the piston, said piston rod 16 leading out of the cylinder 14 for manual operation of the pump 11. The suction side 12 of the pump 11 is connected to the passage 9 of the suction piece 4 via a connection line 17. A manually operable cut-off valve 18, with which the connection line 17 can be opened and closed, is arranged in the connection line 17.

To administer the product, the pump 11 is tensed in a first step, i.e. the piston 15 is retracted in the cylinder 14 and a partial vacuum is thus generated on the suction side 12 of the pump 11. The piston 15 is latched in this position. Then the rim 6' of the device is pressed against the tissue with slight pressure at the point of injection [via the chamber opening rim of the suction chamber V,6,] as already described. In the next step, the valve 18 is opened, such that instantaneous pressure [equalisation] equalization takes place between the suction side 12 of the pump 11 and the suction chamber V [,6] via the connection line 17 and the passage 9. Due to the partial vacuum momentarily resulting in the suction chamber V [,6], the tissue is suctioned into the suction chamber V [,6] and so simultaneously tensed at its surface, [which facilitate penetrating] together facilitating the penetration of the skin by the injection needle 3. The

product is then delivered by activating a delivery means 20. Preferably, suctioning the tissue simultaneously strengthens blood circulation in the suctioned area of tissue and so accelerates the transporting of the delivered product away from the delivery site [of the delivered product] .

Figures 5 and 6 show the administering device from Figure 4 comprising an alternative embodiment and arrangement for a pump 11. The pump in this [example] exemplary embodiment is likewise formed by a piston pump comprising a cylinder 14 and a piston 15 accommodated linearly [movable] moveably in it. The cylinder 14 is fixed to the casing 1 of the device; it can also be an integral component of the casing 1. The longitudinal axis of the cylinder 14 runs parallel alongside the longitudinal axis of the administering device. Due to the immediate spatial proximity, a specific connection line between the suction chamber V [6] and the suction side 12 of the pump 11 is omitted. The passage 9 in the chamber wall 6 leads directly into the cylinder space of the pump 11 which forms the suction side 12. A cut-off valve 18 is arranged in the passage 9 in [this example] the depicted embodiment.

With continued reference to Figures 5 and 6, to [To] operate the pump 11, a piston rod 16 projects from the suction side of the piston 15 and out of the cylinder 14 [in the example embodiment in Figures 5 and 6] . A further rod-shaped formation projects from the pressure side of the piston 15, said formation comprising a locking means 19, for example a locking hook, at its exposed end. To operate the pump, the user pushes the piston rod 16 into the cylinder 14 and thus pushes the piston 15 from the suction side 12 of the pump toward the pressure side 13 of the pump, until the locking means 19 locks with an opposite locking means in the cylinder 14. The pump is now tensed and the administering device is ready for administering the product. By placing the opening rim 6' of the suction chamber V [6] on the tissue and then opening the hitherto still closed cut-off valve 18, the product is administered in the manner already outlined above.

Figure 7 shows an administering device comprising a pump 11 which is directly fixed to the casing 1 or integrally formed with it, as in the [example] embodiment in Figures 5 and 6. The co-operation between the pump 11 and the suction chamber V [6] corresponds to that of the [example] exemplary embodiments already described. The pump 11 itself is formed like the pump of the [example] embodiment in Figures 5 and 6. As opposed to the pump in Figures 5 and 6, however, the pump of the [example] embodiment in Figure 7 is operated as a bilaterally acting pump. The pressure side 13 of the pump 11 is connected to the air-tight sealed inner space of the casing 1 via a pressure line 21. The pressure side 13 acts via the pressure line 21 on the delivery means 20 which in this [example] embodiment is arranged in the sealed inner space of the casing 1.

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Under the pressure of the pump, the delivery means 20 acts as a piston, and the casing 1 acts as a cylinder of said piston. Under the influence of the pump pressure, the delivery means 20 is advanced in the proximal direction, slaving a displacing piston accommodated in the product reservoir 2.

The administering device in Figure 8 is formed by an auto-injection device . The formation of the suction chamber V [6] and the pump and their co-operation again correspond to that of the [example] exemplary embodiments already described. In the [example] exemplary embodiment in Figure 8, the pressure on the pressure side 13 of the pump is used on the one hand, as in the [example] embodiment in Figure 7, to operate the delivery means 20, and on the other hand also to move the injection needle 3 relative to the casing 1. In the [example] embodiment in Figure 8, the injection needle 3 only penetrates the tissue when it is advanced. It would also be conceivable to cause the needle to penetrate [deeper] more deeply by suctioning the tissue and advancing the needle 3.

The administering device of the [example] embodiment in Figure 8 can in particular be formed by an auto-injection device such as is described in DE 198 22 031 (run-off control) of the Applicant, [whose] the disclosure of which is hereby referred to [as] provide an example of a preferred auto-injection device. The mechanical operation of advancing the needle and the mechanical operation of the delivery means of this pre-described administering device are, however, replaced in accordance with the invention by a pneumatic operation, as shown functionally in Figure 8. To this end, the pressure side 13 of the pump is connected to the inner space of the casing 1 via a pressure line 21 and a cut-off valve 26 accommodated in it. A carrier means 25, in which the reservoir 2 and the injection needle 3 connected to it are immovably accommodated, forms a piston which is accommodated linearly [movable] moveably in the casing 1 and on the rear side of which the pressure of the pump acts. The delivery means 20 is accommodated within the carrier means 25, said delivery means 20 including a drive member

22a and a driven member 22b which form a spindle drive in a known manner. The delivery means 20 is accommodated in the carrier means 25 linearly [movable] moveably relative to the carrier means 25, and forms [for its part] a further piston. The pressure space P1 between the casing 1 and the carrier means 25 is connected to the pressure space P2 formed behind the delivery means 20 within the carrier means 25 via a passage 24. The adjustment between the passage 23, which leads into the pressure space P1 for the carrier means 25, and the passage 24, which leads into the pressure space P2 for the delivery means 20, is formed such that the run-off control described in DE 198 22 031 for movement of the carrier means 25 and the delivery means 20 is achieved.

In the foregoing description preferred embodiments of the invention have been presented for the purpose of illustration and description. They are not intended to be exhaustive or to limit the invention to the precise

form disclosed. Obvious modifications or variations are possible in light of the above teachings. The embodiments were chosen and described to provide the best illustration of the principals of the invention and its practical application, and to enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the appended claims when interpreted in accordance with the breadth they are fairly, legally, and equitably entitled.--

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IN THE CLAIMS

Please amend and enter the claims 1-10 to read as follows:

1. (Amended) A suction piece for a device for administering an injectable product, said suction piece [including] comprising:

- a) a suction chamber comprising a [chamber opening] rim via which said suction piece may be placed on a tissue;
- b) a connection [part] portion whereby said suction piece may be mechanically connected to said device [in order to produce a mechanical connection to said device]; and
- c) a first passage extending through said connection [part] portion into said suction chamber [, in order to produce] thereby providing a fluid connection between said suction chamber and a product reservoir of said device;
- d) wherein when said rim is placed on said tissue, the pressure in said suction chamber may be reduced [, when said chamber opening rim is placed on said tissue, in order to] whereby suction is applied to said tissue.

2. (Amended) The suction piece as set forth in claim 1, [characterised in that] wherein a second passage adapted to evacuate said suction chamber extends through said suction piece and opens into said suction chamber [, to evacuate said suction chamber].

3. (Amended) The suction piece as set forth in claim 1, [characterised in that] wherein said first passage is sealed air-tight by [means of] a seal.

4. (Amended) A device for administering an injectable product, said device [including] comprising:

- a) a casing comprising a receptacle for said injectable product;
- b) [and] a dispensing means comprising an opening through which said product may be administered into a tissue;

- c) [wherein said dispensing means comprising said opening opens into] a suction chamber wherein said opening opens into said suction chamber; [and]
- d) [a chamber opening rim of] said suction chamber comprising a rim which may be placed on said tissue; wherein
- e) [and wherein] the pressure in said suction chamber placed on said tissue may be reduced.

5. (Amended) The device as set forth claim 4, [characterised in that] wherein a passage is formed in a wall of said suction chamber, wherein said passage opens via one end into said suction chamber and at another end may be connected [or is connected] to a pump.

6. (Amended) The device as set forth in claim 4, [characterised in that] wherein said suction chamber is formed by a separate suction piece, [and in that] said suction piece [is connected detachably or non-detachably] connectable to said device.

7. (Amended) The device as set forth in claim 4, [characterised in that] wherein said suction chamber is formed by said casing of said device.

8. (Amended) The device as set forth in claim 4, [characterised in that] wherein a pump, which comprises a suction side and a pressure side, is connected on said suction side to said suction chamber and on said pressure side to a delivery means of said device, such that by means of said pump, said suction chamber may be evacuated and said delivery means may be operated in order to deliver said product [, by means of said pump].

9. (Amended) The device as set forth in claim 4, [characterised in that] wherein said dispensing means is an injection needle which may be moved relative to said suction chamber toward said tissue.

10. (Amended) The device as set forth in [the preceding claim, characterised in that] claim 9,
wherein :

said injection needle is connected to a carrier means which may be moved relative to said
casing; and

a pump, which comprises a suction side and a pressure side, is connected on said suction side to
said suction chamber and on said pressure side to said carrier means, such that said suction
chamber may be evacuated and said carrier means may be moved by the pressure on said
pressure side of said pump toward said tissue, by means of said pump.

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